



May 11, 2026

Velmeni, Inc.
% Mini Suri
Chief Executive Officer
333 W. Maude Ave, STE 207
SUNNYVALE, CA 94085

Re: K252953

Trade/Device Name: Velmeni for Dentists (V4D) Endo-Perio
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: April 9, 2026
Received: April 10, 2026

Dear Mini Suri:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252953

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Please provide the device trade name(s).

?

Velmeni for Dentists (V4D) Endo-Perio

Please provide your Indications for Use below.

?

VELMENI for DENTISTS (V4D) Endo-Perio is a concurrent-read, computer-assisted detection software intended to assist dentist in the clinical detection of tooth anatomy (enamel, dentine in crown, pulp, and root) , jaw anatomy (mental foramen, inferior alveolar canal, and maxillary sinus) , bone level(cementoenamel junction and crestal bone) and root canal treated tooth(RCT) in digital bitewing, periapical and panoramic radiographs of permanent teeth in patients 15 years of age or older. This device provides additional information for dentists in examining radiographs of patients' teeth.

This device is not intended as a replacement for a complete examination by the dentist or their clinical judgment that considers other relevant information from the image, patient history, or actual in vivo clinical assessment. Final diagnoses and patient treatment plans are the responsibility of the dentist.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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VELMENI for DENTISTS (V4D) Endo-Perio
K252953
510(k) Summary

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the following 510(k) Summary for VELMENI for DENTISTS (V4D) is provided:

Submitter Information

Submitter: Velmeni Inc.
333 West Maude Avenue, STE 207
Sunnyvale, CA 94085
Phone: 201-289-3500

Date Prepared: May 11, 2026

Contact Person: Mini Suri, CEO
Velmeni Inc.
Phone: 201-289-3500
Email: mini@velmeni.com

Identification of the Device

Trade Name: VELMENI for DENTISTS (V4D) Endo-Perio
Common Name: Medical image analyzer
Classification Name: Medical image analyzer
21CFR892.2070

Product Code: MYN
Device Class: Class II

Predicate Device(s)

Predicate Device: Velmeni for Dentists (K240003)
Reference Device: Overjet Charting Assist(K233590)
Reference Device: Denti.AI Detect (K230144)

Device Description

VELMENI for DENTISTS (V4D) Endo-Perio software medical device comprises of the following key components:

- Web Application Interface delivers front-end capabilities and is the point of interaction between the device and the user. Users may edit the outputs of the model.
- Machine Learning (ML) Engine delivers V4D Endo-Perio's core ML capabilities through the radiograph type classifier, rotation classifier , tooth numbering module, root canal treated tooth (RCT) module, tooth anatomy module, jaw anatomy module, and merging module. These functionalities are added to the previously cleared CAde device, Velmeni for Dentists (K240003)
- Backend API allows interaction between all the components, as defined in this section, in order to fulfill the user's requests on the web application interface.

- Queue receives and stores messages from Backend API to send to AI-Worker.
- AI-Worker accepts radiograph analysis requests from Backend API via the Queue, passes gray scale radiographs to the ML Engine in the supported extensions (jpeg and png), and returns the ML analysis results to the Backend API.
- Database and File Storage store critical information related to the application, including user data, patient profiles, analysis results, radiographs, and associated data.

The following non-medical interfaces are also available with VELMENI for DENTISTS (V4D) Endo-Perio:

- VELMENI BRIDGE (VB) acts as a conduit enabling data and information exchange between Backend API and third-party software like Patient Management or Imaging Software
- Rejection Review (RR) module captures the ML-detected conditions rejected by dental professionals to aid in future product development and to be evaluated in accordance with VELMENI's post-market surveillance procedure.

Intended Use/ Indications for Use

VELMENI for DENTISTS (V4D) Endo-Perio is a concurrent-read, computer-assisted detection software intended to assist dentist in the clinical detection of tooth anatomy (enamel, dentine in crown, pulp, and root) , jaw anatomy (mental foramen, inferior alveolar canal, and maxillary sinus) , bone level(cementoenamel junction and crestal bone) and root canal treated tooth(RCT) in digital bitewing, periapical and panoramic radiographs of permanent teeth in patients 15 years of age or older. This device provides additional information for dentists in examining radiographs of patients' teeth.

This device is not intended as a replacement for a complete examination by the dentist or their clinical judgment that considers other relevant information from the image, patient history, or actual in vivo clinical assessment. Final diagnoses and patient treatment plans are the responsibility of the dentist.

Substantial Equivalence and Technological Comparison

The proposed **VELMENI for DENTISTS (V4D) Endo-Perio** device is substantially equivalent to the primary predicate device; VELMENI for DENTISTS(K240003). Two reference devices were identified, Overjet Charting Assist (K233590) and Overjet Dental Assist (K210187).

The proposed **VELMENI for DENTISTS (V4D) Endo-Perio** is a concurrent-read, computer-assisted detection software intended to assist dentist in the clinical detection of tooth anatomy (enamel, dentine in crown, pulp, and root) , bone level(cementoenamel junction and crestal bone) , jaw anatomy (mental foramen, inferior alveolar canal, and maxillary sinus), and root canal treated tooth(RCT) in digital bitewing, periapical and panoramic radiographs of permanent teeth in patients 15 years of age or older. Users may edit the output segmentations and bone level landmarks of the model. 2D Non-Pathologies introduced in the proposed device will be accessible as a functionality from the existing **V4D Analyze Page** . The underlying architecture of device components between predicate and proposed device is the same.

The major difference between the proposed device and the predicate devices is that the proposed

device's output adds detection and segmentation capabilities for tooth anatomy, jaw anatomy, bone level and root canal treated tooth in the ML engine component versus the predicate device's output has detection of dental caries, restorations, fixed prostheses, and implants. Reference devices, **K233590 Overjet Charting Assist**, and **K230144 Denti.AI Detect** were identified because they demonstrate the Agency's familiarity with computer-assisted technology's ability to identify and detect anatomical regions introduced in the proposed device. The test methods used by **V4D Endo-Perio** to evaluate safety and effectiveness of the proposed device are acceptable. The differences in the software were evaluated against predetermined acceptance criteria and demonstrated acceptable results. The proposed device's output was evaluated in standalone performance testing to demonstrate the safety and effectiveness of the device.

Performance Data

Software Verification and Validation Tests:

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submission for Device Software Functions." Verification of the software was conducted to ensure that the product works as designed. Validation was conducted to validate the design and the performance of the device to meet user needs and intended uses. VELMENI FOR DENTISTS (V4D) Endo-Perio passed all verification and validation software tests. Overall, the VELMENI for DENTISTS (V4D) Endo-Perio was found to be safe and effective for all intended users, uses, and use environments.

Cybersecurity:

Software verification and validation testing, and cybersecurity testing per FDA guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", were conducted to ensure that the software meets its specifications and performs as intended.

Bench Testing:

The standalone analyses confirmed that the device exceeded the performance goals of tooth anatomy detection for the tooth and root canal treated tooth primary analyses and for the bone level analyses.

The software was tested on a dataset of the following composition: Bitewing tooth anatomy analyses were performed on a set of 128 patients, 272 images, and 1791 teeth. Periapical tooth anatomy analyses were performed on a set of 137 patients, 271 images, and 1213 teeth. Panoramic jaw anatomy analyses were performed on a set of 245 patients, 248 images, and 496 sides. A total of 137 root canal images were used for all root canal analyses which were provided by 89 bitewing patients, 110 periapical patients, and 134 panoramic patients. Bitewing bone level analyses were performed on a set of 193 patients and images and 1067 teeth. Periapical bone level analyses were performed on a set of 186 patients and images and 492 teeth.

The ground truth was assessed by three US-licensed dentists with more than 5 years of experience and a US licensed dental radiologist with advanced training in Oral and Maxillofacial Radiology. The three ground-truthers provided their segmentations and labels for each instance of interest, without consulting one another. The final ground truth was derived through the majority rule, and, for any radiograph in which such a consensus could not be derived, a dental radiologist (adjudicator)

considered all annotations by the 3 ground truthers and made the final independent ground-truthing decision. A consensus is defined when the intersection over union (IOU) of ground truthers' localizations is at least 70%, and the labels of these overlapping localizations are the same.

The primary tooth endpoints of sensitivity and mean FPR per image produced p-values less than <0.001 across dentine crown, enamel, pulp, and root for both bitewing and periapical images; indicating that tooth analysis had a sensitivity $\geq 85\%$ and a FPR per image ≤ 0.50 . The primary root canal endpoints of sensitivity and specificity produced p-values less than <0.001 across the bitewing, periapical, and panoramic image types, indicating that the performance goals were surpassed and that sensitivity $\geq 80\%$ and specificity $\geq 85\%$. The primary bone level endpoint of mean absolute error produced p-values of <0.001 when compared to the performance goal of 0.5 mm error tolerance for all comparisons. All segmentation outputs and bone level landmarks may be edited by the end user, as needed.

Table 1, Tooth Anatomy Primary Endpoint Sensitivity Analysis, Bitewing Images

	Sensitivity		
	% (n/N)	95% CI ¹	P-value ²
Dentine Crown	100.0% (1743/1743)	NA, NA	NA
Enamel	94.4% (1673/1773)	92.6%, 96.0%	<0.001
Pulp	99.5% (1652/1661)	98.8%, 99.9%	<0.001
Root	98.4% (1748/1777)	97.6%, 99.0%	<0.001

Table 2, Tooth Anatomy Primary Endpoint Sensitivity Analysis, Periapical Images

	Sensitivity		
	% (n/N)	95% CI ¹	P-value ²
Dentine Crown	97.9% (1139/1164)	96.8%, 98.7%	<0.001
Enamel	96.2% (1126/1170)	94.8%, 97.5%	<0.001
Pulp	99.6% (1121/1126)	99.1%, 99.9%	<0.001
Root	99.8% (1208/1210)	99.6%, 100.0%	<0.001

Table 3, Tooth Anatomy Primary Endpoint FPR Per Image, Bitewing Images

	False Positive Rate	
	% (n/N)	P-value ²
FP Counts per Dentine Crown Image, n (%) None	100.0% (272/272)	
FP Counts per Dentine Crown Image Mean (SD) 95% CI ¹	0 (NA) NA, NA	NA
FP Counts per Enamel Image, n (%) None 1 2 3	73.5% (200/272) 18.8% (51/272) 5.1% (14/272) 2.6% (7/272)	
FP Counts per Enamel Image Mean (SD) 95% CI ¹	0.26 (0.442) 0.20, 0.34	<0.001

	False Positive Rate	
	% (n/N)	P-value ²
FP Counts per Pulp Image, n (%)		
None	97.1% (264/272)	
1	2.6% (7/272)	
2	0.4% (1/272)	
FP Counts per Pulp Image		
Mean (SD)	0.03 (0.169)	<0.001
95% CI ¹	0.01, 0.06	
FP Counts per Root Image, n (%)		
None	90.8% (247/272)	
1	8.1% (22/272)	
2	0.7% (2/272)	
3	0.4% (1/272)	
FP Counts per Root Image		
Mean (SD)	0.09 (0.289)	<0.001
95% CI ¹	0.06, 0.13	

Table 4, Tooth Anatomy Primary Endpoint FPR Per Image, Periapical Images

	False Positive Rate	
	% (n/N)	P-value ²
FP Counts per Dentine Crown Image, n (%)		
None	91.8% (247/269)	
1	7.4% (20/269)	
2	0.4% (1/269)	
3	0.4% (1/269)	
FP Counts per Dentine Crown Image		
Mean (SD)	0.08 (0.275)	<0.001
95% CI ¹	0.05, 0.12	
FP Counts per Enamel Image, n (%)		
None	86.5% (230/266)	
1	10.9% (29/266)	
2	2.3% (6/266)	
3	0.4% (1/266)	
FP Counts per Enamel Image		
Mean (SD)	0.14 (0.343)	<0.001
95% CI ¹	0.09, 0.18	
FP Counts per Pulp Image, n (%)		
None	98.9% (268/271)	
1	1.1% (3/271)	
FP Counts per Pulp Image		
Mean (SD)	0.01 (0.105)	<0.001
95% CI ¹	0.00, 0.03	
FP Counts per Root Image, n (%)		
None	99.3% (269/271)	
1	0.7% (2/271)	
FP Counts per Root Image		
Mean (SD)	0.01 (0.086)	<0.001
95% CI ¹	0.00, 0.02	

Table 5, Bone Level Mean Absolute Error Analysis, Bitewing and Periapical Images

	Bitewing Images		Periapical Images	
	Mean (95% CI) ¹	P-value ¹	Mean (95% CI) ¹	P-value ¹
Distal Error	0.15 (0.13, 0.17)	NA	-0.04 (-0.11, 0.03)	NA
Distal Absolute Error	0.25 (0.23, 0.26)	<0.001	0.44 (0.39, 0.49)	<0.001
Mesial Error	0.17 (0.14, 0.19)	NA	-0.05 (-0.13, 0.03)	NA
Mesial Absolute Error	0.27 (0.25, 0.29)	<0.001	0.47 (0.42, 0.52)	<0.001

The standalone primary analysis for jaw anatomy indicates the Mandibular Canal and Maxillary Sinus anatomical features reached the sensitivity and FPR per image estimates, with Mandibular Canal estimates of 99.8% and 0.00 (p-values <0.001), and Maxillary Sinus estimates of 99.8% and 0.00 (p-values of <0.001 generated for both). For the Mental Foramen tooth anatomy, a sensitivity estimate of 81.5 % was produced with a 95% CI of 77.7 %, 85.3% and a p-value of 0.220. For the FPR co-primary endpoint, an estimate of 0.18 with a 95% CI of 0.13, 0.23 and a p-value of <0.001 was produced. All segmentation outputs may be edited by the end user, if needed. Panoramic images are used for general examination and prescreening of the mandible due to low cost, ease of use and ability to cover an area. For procedures involving higher accuracy, advanced imaging would be followed up by dentists in practice and is indicated in the instructions for use to notify device users.

Table 6, Panoramic View Features Primary Endpoint Sensitivity Analysis, Panoramic Images

	Sensitivity		
	% (n/N)	95% CI ¹	P-value ²
Mandibular Canal	99.8% (495/496)	99.4%, 100.0%	<0.001
Mental Foramen	81.5% (393/482)	77.7%, 85.3%	0.220
Maxillary Sinus	99.8% (495/496)	99.4%, 100.0%	<0.001

Subgroup analyses were conducted across subject sex, age, and sensor type. In the subgroup analyses, across all three analyses there was never a case of one subgroup factor performing significantly better or worse than any other subgroup levels within the same subgroup, as each 95% CI always overlapped with at least one of the other subgroup level 95% CI's when it was available. There was no consistent trend of subgroup performance that affected multiple different endpoints.

Generalizability was ensured through independence of the test set and representation across the subgroups within the data. The patient and teeth demographics for the study are well-represented. There was sufficient tooth anatomy, sensor, study site representation.

Conclusion

Both the predicate device and the proposed VELMENI for DENTISTS (V4D) Endo-Perio device share the same intended purpose. Despite minor technological differences, these differences in technological features do not raise concerns regarding safety or effectiveness. Following the information reviewed as part of this 510k, it can be concluded that the VELMENI for DENTISTS (V4D) Endo-Perio is substantially equivalent to the predicate device.